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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 11/29/2001 Taiichiroh Meguro 049400-5021 9139 09/995,789 **EXAMINER** 9629 7590 12/23/2004 MORGAN LEWIS & BOCKIUS LLP FOREMAN, JONATHAN M 1111 PENNSYLVANIA AVENUE NW ART UNIT PAPER NUMBER WASHINGTON, DC 20004 3736

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
Office Action Summary	09/995,789	MEGURO ET AL.	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) Responsive to communication(s) filed on <u>04 October 2004</u> .			
2a)⊠ This action is FINAL . 2b)☐ This	,—		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) Claim(s) 1.3 and 13 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1.3 and 13 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.			
Application Papers			
9) The specification is objected to by the Examiner.			
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 			
Attachment(s)			
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:		

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DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Page 8, line 2 states, "ellipsoidal helical spring is". Reference numeral "3" should follow "ellipsoidal helical spring". Page 14, line 25 states, "attach o the". This should read "attach to the".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,465,733 to Hinohara et al. in view of U.S. Patent No. 5,368,048 to Stoy et al.

In regards to claims 1 and 2, Hinohara et al. discloses a guide wire (20) having a front catheter engagement portion (26) formed from a barrel portion. A provisionally connected balloon catheter (40) is inserted into a coronary artery with the guide wire (Col. 8, lines 48 – 51). The barrel portion is formed by soldering a portion in one piece on a helical spring (24) portion of the guide wire and a core (22) inserted in the guide wire (Col. 6, lines 2 – 4). The front end of the catheter (42) is shown to be diametrically smaller than a maximum diameter of the barrel portion (Figure 3). It is inherent that the flexible catheter that if forced in a distal direction over the barrel portion (26), the tip (42) would deform to be diametrically greater than a tube portion of the catheter and would have a flared end portion. The barrel portion must have been cut at its outer surface during the

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shaping of the barrel. Hinohara et al. discloses the barrel portion being formed of stainless steel (Col. 5, lines 65 - 67), but does not disclose the stainless steel having a mirror-finish. Stoy et al. discloses a guide wire and teaches that it is well know in the art to provide stainless steel with a mirror finish in order to reduce friction (Col. 1, lines 49 - 51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the barrel portion as taught by Hinohara et al. to include a mirror finish as taught by Stoy et al. in order to reduce the friction on the outer surface of the barrel portion so as not to hinder the guide wire as it penetrates tight passages (Col. 1, lines 40 - 48).

Response to Arguments

4. Applicant's arguments filed 10/4/04 have been fully considered but they are not persuasive. In response to the Specification objection, the Examiner maintains that page 8, line 2 states, "ellipsoidal helical spring is", and that reference numeral "3" should follow "ellipsoidal helical spring". The Examiner notes that "3" already follows "ellipsoidal helical spring" on line 3 of Page 8. Additionally, the Examiner agrees that there is no page 23 of the specification and would like to point out the objection is directed to page 14, line 25 of the specification which states "attach o the". Applicant has asserted that neither Hinohara et al. or Stoy et al. disclose the features recited in claim 1, specifically "a front end of the balloon catheter is diametrically smaller than a maximum diameter of the mirror-finished barrel portion, and elastically deforms to be diametrically greater than a tube portion of the balloon catheter so as to be a flared end portion when the mirror-finished barrel portion engages with the front end of the balloon catheter in accompany with provisionally connecting the balloon catheter". Moreover, Applicant asserts that neither Hinohara et al. nor Stoy et al. teach or suggest that a balloon catheter engages a guide wire. However, the Examiner disagrees. As Applicant has pointed out, the word engages suggests that the balloon catheter (40)

and the barrel portion (26) of the guide wire (20) must be interlocked together. Hinohara et al. discloses such a feature. "Interlock" as defined by Merriam-Webster's Collegiate Dictionary 10th ed. means to unite; to connect so that the motion or operation of any part is constrained by another. Hinohara et al. teaches the barrel portion (26) interlocking with the guide wire (20; Col. 7, lines 30 – 33). Here the barrel portion (26) interlocks with the catheter (40) to keep the guide wire centered within the catheter. Hence, if the barrel portion and the catheter were not connected so that the motion of the guide wire was not constrained by the catheter, then the guide wire would not remain centered within the lumen of the catheter (40). Additionally, the front end of the catheter (42) is shown to be diametrically smaller than a maximum diameter of the barrel portion (Figure 3). It is inherent to the flexible catheter that if forced in a distal direction over the barrel portion (26), the tip (42) would deform to be diametrically greater than a tube portion of the catheter and would have a flared end portion.

Allowable Subject Matter

5. Claim 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. No prior art discloses or fairly suggests a guide wire having a mirror-finished barrel portion with two parallel flat sections lengthwise on the barrel.

Conclusion

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the

THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IMLF

MAX F. HINDENBURG